IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 09/693,121

Applicant: Schlom et al.

Filed: October 20, 2000

TC/AU: 1643

Examiner: Christopher H. Yaen

Docket No.: 701319 (Client Reference No. E-200-1990/4-US-06)

Customer No.: 45733

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

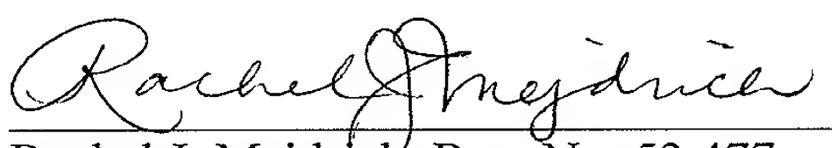
Dear Sir:

Appellants request review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the following sheets.

Respectfully submitted,



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Date: July 2, 2008

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Status of Claims

Claims 17, 20, 22, 25-31, 34, and 36-42 are pending and are the subject of this appeal.

Summary of Claimed Subject Matter

The appealed claims are directed to a method for generating a cytotoxic T-cell eliciting immune response to prostate-specific antigen (PSA) in a human host. The method comprises (i) administering to the host a first pox virus vector having at least one insertion site containing a DNA segment encoding PSA or a cytotoxic T-cell eliciting epitope thereof operably linked to a promoter such that the DNA segment is expressed to produce PSA or the cytotoxic T-cell eliciting epitope thereof in the host in a sufficient amount to generate a cytotoxic T-cell eliciting immune response, and (ii) then administering an additional PSA or T-cell eliciting epitope thereof in a manner selected from the group consisting of in a second pox virus vector, in a formulation with an adjuvant, with a cytokine, with a co-stimulatory molecule, in a liposomal formulation, and a combination thereof (see, e.g., the specification at page 3, line 24, through page 4, line 7; and page 10, line 20, through page 11, line 7).

Grounds of Rejection to be Reviewed

Claims 17, 25, 26, 28, and 37-42 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Spitler et al. (U.S. Patent 5,925,362).

Claims 17, 20, 22, 25-31, 34, and 36-42 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Spitler et al. in view of (i) Fields Virolgy, 3rd Edition, Vol. 2, Lippincott, Williams, and Wilkins, pages 2637-2671, 1996 (Fields '96) or Fundamental Virology, 2nd Edition, Raven Press, pages 953-973, 1991 (Fields '91) and (ii) Hodge et al. (*Cancer Research, 54(21)*: 5552-5555 (1994)).

Reasons for Withdrawal of the Anticipation Rejection

The appealed claims are directed to a method for generating a cytotoxic T-cell eliciting immune response to PSA in a human host. The method comprises two steps: (i) administering to the host a first pox virus vector having at least one insertion site containing a

DNA segment encoding PSA or a cytotoxic T-cell eliciting epitope thereof operably linked to a promoter such that the DNA segment is expressed to produce PSA or the cytotoxic T-cell eliciting epitope thereof in the host in a sufficient amount to generate a cytotoxic T-cell eliciting immune response, and (ii) then administering an additional PSA or T-cell eliciting epitope thereof in a manner selected from the group consisting of in a second pox virus vector, in a formulation with an adjuvant, with a cytokine, with a co-stimulatory molecule, in a liposomal formulation, and a combination thereof.

The Office contends that Spitler et al. teaches a method of inducing an anti-tumor immune response comprising the administration of a formulation comprising PSA (e.g., in a pox viral vector) and cytokines, wherein the formulation can be administered more than once as booster inoculations (see paragraph bridging pages 3-4 of the Office Action dated January 21, 2004). Based on this disclosure, the Office contends that Spitler et al. anticipates the appealed claims.

Spitler et al. is considered to be prior art under Section 102(e). A reference that is considered prior art under Section 102(e) can be removed as prior art by the submission of evidence of an invention date before the earliest effective date of the reference (in this instance, before August 11, 1993).

Appellants submitted a first Declaration Under 37 C.F.R. § 1.131 ("first declaration") with the Amendment dated November 28, 2005. The first declaration provides evidence that prior to the earliest effective date of Spitler et al. (i.e., August 11, 1993), Appellants conceived of a recombinant pox virus comprising a PSA gene inserted into a HindIII restriction site for the manufacture of a clinical vaccine (see the table on the first page, and the paragraph bridging the first and second pages, of Exhibit A of the first declaration). The PSA gene is under the transcriptional control of the vaccinia 40K promoter and results in the expression of PSA (see paragraph 1 of the first page, and paragraph 1 of the second page, of Exhibit A of the first declaration). The first declaration supports Appellants' conception of utilizing PSA in a recombinant pox virus vector to generate an immune response (see paragraph 10 of the first declaration).

With the Reply to Office Action dated October 27, 2007, Appellants submitted a second Declaration Under 37 C.F.R. § 1.131 ("second declaration") that demonstrates that prior to the earliest effective date of Spitler et al. (i.e., August 11, 1993), Appellants conceived of the idea of generating an immune response to PSA by administering a pox virus vector encoding PSA followed by a second pox virus vector encoding PSA or a PSA antigen in a prime and boost protocol.

In particular, Exhibit A of the second declaration, which is a Material Transfer Agreement (MTA), details two pox virus vectors (vaccinia and fowlpox) in which a human tumor associated antigen is to be inserted. Exhibit A indicates that the vectors will be used for clinical grade vaccine production.

Exhibit B of the second declaration is a MTA that details a PSA (a tumor-associated antigen) clone to be used in the production of a clinical grade vaccine.

Exhibit C of the second declaration is an Agenda for a site visit at the Laboratory of Tumor Immunology and Biology. The Agenda includes a description of the administration of a pox virus vector encoding PSA, such as a recombinant vaccinia PSA or avipox-PSA construct (see, e.g., page 32, paragraph 2, and page 40, paragraph 2, of Exhibit C). The first administration can be followed by at least a second administration of a pox virus vector encoding PSA or immunogenic PSA peptides emulsified with the adjuvant, DETOX, or in a liposomal formulation (see, e.g., page 40, paragraph 2, and paragraph bridging pages 40-41, of Exhibit C). Exhibit C also describes the use of cytokines to enhance anti-PSA T cell responses (see, e.g., paragraph bridging pages 40-41).

Appellants have provided evidence commensurate in scope with the appealed claims that the claimed invention was conceived prior to the earliest effective date of Spitler et al. (i.e., August 11, 1993). The first declaration provides evidence of the conception of a pox viral vector containing an insertion site containing a DNA segment encoding PSA or a cytotoxic T-cell eliciting epitope thereof (e.g., the PSA gene) operably linked to a promoter (e.g., vaccinia 40K promoter), such that the DNA segment is expressed to produce PSA or a cytotoxic T-cell eliciting epitope thereof to generate an immune response. The second declaration provides evidence of the conception of a method to generate an immune response

by administering a pox viral vector (e.g., recombinant vaccinia virus) encoding PSA followed by the administration of PSA or a T-cell eliciting epitope thereof (e.g., in a pox viral vector, with an adjuvant, with a cytokine, and in a liposomal formulation).

For these reasons, Spitler et al. cannot be considered to be prior art to the appealed claims, and Appellants request that the anticipation rejection be withdrawn.

Reasons for Withdrawal of the Obviousness Rejection

As discussed above, the Office contends that Spitler et al. discloses a method of inducing an anti-tumor immune response comprising the administration of a formulation comprising PSA (e.g., in a pox viral vector) and cytokines, wherein the formulation can be administered more than once as booster inoculations. The Office acknowledges that Spitler et al. does not disclose specific types of pox viruses, such as suipox, avipox (fowlpox, canary pox, or pigeon pox), and capripox, or B7.1 and B7.2 co-stimulatory molecules (see page 5, last paragraph, of the Office Action dated January 21, 2004). However, the Office contends that the deficiencies of Spitler et al. are remedied by the disclosures of (i) Fields '96 or Fields '91 ("the Fields references") and (ii) Hodge et al. (see page 5, last paragraph, of the Office Action dated January 21, 2004).

As discussed in relation to the anticipation rejection, Spitler et al. cannot be considered to be prior art to the appealed claims. The Office relies upon the Fields references for the disclosure of different types of pox viruses and to provide the motivation of using pox viruses for gene transfer (see page 5, paragraph 1, of the Office Action dated January 21, 2004, and paragraph bridging pages 4-5 of the Office Action dated June 6, 2005). The Office relies upon Hodge et al. for the disclosure of B7.1 and B7.2 co-stimulatory molecules and their specific anti-tumor immune response elicitation in pox viral vectors (see page 5, paragraph 1, of the Office Action dated January 21, 2004). Thus, the Fields references and Hodge et al. merely provide a general disclosure of pox viruses and co-stimulatory molecules, respectively. Without the disclosure of Spitler et al., the Fields references and Hodge et al., either alone or in combination, do not render obvious the subject matter of the appealed claims.

Thus, Appellants request that the obviousness rejection be withdrawn.